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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,809	05/04/2001	Mark W. Perlin	PERLIN-10	8918
7590	03/02/2006		EXAMINER	
Ansel M. Schwartz Attorney at Law Suite 304 201 N. Craig Street Pittsburgh, PA 15213			SMITH, CAROLYN L	
			ART UNIT	PAPER NUMBER
			1631	
DATE MAILED: 03/02/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,809

Applicant(s)

PERLIN, MARK W.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8,9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8,9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed 12/15/05, has been entered.

Amended claims 1 and 11, filed 12/15/05, are acknowledged.

Claims herein under examination are 1-4, 8-9, and 11-12.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8-9, and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There does not appear to be adequate written support for the phrase "or higher" in amended claims 1 (line 8) and 11 (line 10). Applicant points to support on page 21, lines 1-6, of the specification. This section of the specification fails to mention second, third, and higher

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dimensions. Because introduction of the phrase “or higher” does not appear to have written support, this phrase is considered to be NEW MATTER. Claims 2-4, 8-9, and 12 are also rejected due to their dependency from claims 1 and 11.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8-9, and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 (lines 6-9) and 11 (lines 8-11) recite the limitation “detecting a total amount of label present in the collection to produce a measurement that is determined without performing a one or higher dimensional DNA size separation on the products” which is vague and indefinite. First, it is unclear what this step (of claim 1) and means (of claim 11) is actually claiming. It is unclear if the “amount” is the “measurement”, if one is taking the amount to calculate a measurement, or various other scenarios. Second, it is unclear in what manner the “without performing” phrase is limiting these claims. Is the “without performing” limiting the measurement, the detecting, some sort of calculation, or the entire method? Clarification of this issue via clearer claim wording is requested. Claims 2-4, 8-9, and 12 are also rejected due to their dependency from instant claims 1 and 11.

Claim 8 recites the limitation “is used for criminal justice applications” which is vague and indefinite. This limitation is a passive step. It is unclear what active method step is intended

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to be represented by this limitation. It is also unclear in what manner (i.e. steps) the information is to be applied to the criminal justice applications. Clarification of this issue via clearer claim wording is requested.

Claim 9 recites the limitation “is used in conjunction with” which is vague and indefinite. This limitation is a passive step. It is unclear what active method step is intended to be represented by this limitation. For example, are the data intended to be mathematically combined with the database for mathematical additions, are the data intended to be combined with the database to undergo statistical analysis, or are the data combined with the database merely to update or store more data? Clarification of this issue via clearer claim wording is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheeseman (US 5,302,509).

Cheeseman discloses a method of sequencing polynucleotides (title and abstract). Cheeseman discloses amplifying a nucleic acid sample by polymerase chain reaction techniques to create many DNA molecules (col. 3, fourth and fifth paragraphs) which represents the amplifying step (a) of instant claims 1 and 11. Cheeseman discloses using a primer bound to the

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DNA and extending the growing oligonucleotide chain with four fluorescently labeled 3'-blocked nucleotide triphosphates (NTPs) (col. 3, line 65 to col. 4, line 22 and col. 4, lines 63-68) which represents the extending a sequencing primer bound to the DNA product in the presence of terminating nucleotide analogs to produce a collection of labeled nucleic acid products, as stated in step 1(b) of instant claims 1 and 11. Cheeseman discloses each of the NTPs types (A, G, C, and T NTPs) will be labeled differently so as to be distinguishable by fluorescent spectroscopy or other optical means (col. 4, lines 5-10), identifying the labeled NTP in the DNA strand and repeating these steps until labeled NTPs can no longer be added (col. 2, lines 52-56 and 64-68) wherein the whole sequencing cell (chamber) with optical detection on a planar integrated optical system can be produced by photolithographic means and the planar optics allows many sequencing cells to be produced on the same substrate and illuminated by the same light source (col. 6, lines 58-66) which represents the detecting a total amount of label present in the collection to produce a measurement that is determined without performing a one or higher dimensional DNA size separation on the products, as stated in step (c) of instant claims 1 and 11. Cheeseman discloses repeating the exposure of the four labeled NTPs to the sequence to add another base at each cycle to the growing oligonucleotide thereby identifying the next base until identification is complete (col. 7, third paragraph) with a DNA length example (col. 7, line 54) which represents combining a plurality of measurements to determine the DNA sequence information about the sample (as stated in step (d) of instant claims 1 and 11) as well as DNA sequence information corresponding to the length and plurality of bases in the DNA sequence (as stated in instant claims 3 and 4). Cheeseman discloses only one of the four NTP types being added at a time and read by its fluorescence (col. 5, lines 28-31), adjusting concentrations of

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bound NTPs with DNA such that there is a sufficient number of fluorescent molecules for optical detection (col. 5, lines 41-48) as well as dye concentrations in small areas to improve detection of fluorescence by improving signal-to-noise ratio (col. 6, lines 40-46) which represents each label measurement corresponds to an amount of terminating nucleotide, as stated in instant claim 2. Cheeseman discloses a solid-supported DNA, planar integrated optical system, optical fiber attached to DNA, fluorescent output detection by PIN photodiodes, and flow system (col. 6, lines 30-68; col. 7, fourth and fifth paragraphs) which represent the system for nucleic acid sequencing, as stated in instant claim 11.

Thus, Cheeseman anticipates instant claims 1-4 and 11.

Applicant's arguments with respect to the 35 USC 102(b) rejection have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8, 9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheeseman (US 5,302,509) as applied to claims 1-4 and 11 above; taken in view of Schumm et al. (US 20020012924).

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Cheeseman discloses the limitations of instant claims 1-4 and 11 as stated in the 102 rejection above. Cheeseman does not describe using DNA sequence information for criminal justice applications (instant claim 8), DNA information used in conjunction with a DNA database of genetic polymorphisms (instant claim 9), a PCR thermocycler (instant claim 12), or a computing device with a memory (instant claim 12).

Schumm et al. describe DNA sequencing with PCR including using a thermocycler (paragraphs 0089-0090), as stated in instant claim 12. Schumm et al. describe using DNA profiling for criminal justice applications (paragraph 0013), as stated in instant claim 8. Schumm et al. describe using DNA information with databases including genetic polymorphism data (paragraph 0012), as stated in instant claim 9. Schumm et al. describe using an ABI 377 Sequencer including putting data into a database using computer software (paragraph 0096) and scanning and analyzing for polymorphisms using Hitachi FMBIO fluorescent scanner with accompanying software (paragraph 0100) which represents a computing device with memory, as stated in instant claim 12.

Schumm et al. state DNA typing is commonly employed to identify the source of blood, saliva, semen, and other tissue found at a crime scene (paragraph 0004). Cheeseman state that his DNA sequencing method requires only small quantities of DNA for high sensitivity detection (col. 1, last paragraph). It would have been obvious to the person of ordinary skill in the art at the time the invention was made to analyze the small quantities for DNA sequencing, as stated by Cheeseman, with the databases and computing devices for criminal justice applications, as stated by Schumm et al., because this offers significant improvement over existing technology, bringing increased power and precision to DNA profiling for linkage analysis, criminal justice,

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paternity testing, and other forensic and medical uses, as stated by Schumm et al. (paragraph 0013). The person of ordinary skill in the art at the time the invention was made would have been motivated to make this modification in order to eliminate ambiguity in short DNA sequences, as stated by Cheeseman (col. 2, first paragraph) in forensic analysis which often require determination of whether more than one source of DNA sample is present, as stated by Schumm et al. (paragraph 0010). One of ordinary skill in the art would have expected success as both Cheeseman and Schumm et al. sequence DNA using PCR methods and Schumm et al. states their ability to identify and analyze particular polymorphic loci of DNA of various types, including single-stranded and double-stranded DNA from a variety of different sources (paragraph 0013).

Thus, Cheeseman in view of Schumm et al. make obvious the instant invention.

Applicant's arguments with respect to the 35 USC 103(a) rejection have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)

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(See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

February 21, 2006



Carolyn Smith
Examiner
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